

PRE-CLINICAL TO PHASE III UPSTREAM PROCESS CHANGES TO SUPPORT NEXT GENERATION MANUFACTURING

Sarwat Khattak, Biogen
sarwat.khattak@biogen.com

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From pre-clinical to Phase III, Biogen's upstream process for a recombinant protein underwent a number of process changes. The changes made were dependent on understanding what modulated product quality based on process knowledge and leveraged that knowledge to ensure comparability. The goals were to increase productivity and develop a high throughput next generation manufacturing process. The process changes demonstrated that higher productivity yields combined with advanced process controls can achieve product comparability. Lastly, the process changes were implemented with an 8X scale up. This talk will go over the changes made in the upstream cell culture process and what was monitored and evaluated to support the comparability in protein quality attributes.